

K093688

FEB - 4 2010

510(k) SUMMARY



Canon

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Page 1 of 2, 510(k) Summary: Canon Dynamic/Static DR  
Fluoroscopic Digital X-Ray System  
Model URS-50RF

Date Prepared	October 30, 2009
Summary prepared by:	Chris Duca, Chief Operating Officer
Device Name	Canon Dynamic/Static DR Fluoroscopic Digital X-Ray System
Trade Name	Model URS-50RF
Common Name	Fluoroscopic Digital X-Ray System
Classification	Class: II Product Code: OWB, JAA, 121 Regulation: 21 CFR § 892.1650
Identification of Predicate Devices and Summary of Substantial Equivalence	Siemens AXIOM Luminos dRF, K062623, GE Innova 4100, K023178/K091658, Canon CXDI-50C K060433, Sedecal X-PLUS LP Plus Digital Diagnostic X-Ray Systems K090238 and Canon Dynamic/Static DR Model CXDI-50RF, K092439
Device Description	The Canon Dynamic/Static DR URS-50RF is a portable digital radiography that can take images of any part of the body. It directly converts the X-ray images captured by the LANMIT (Large Area New MIS Sensor and TFT) sensor into high-resolution digital images. The instrument is suited for use inside a patient environment. This unit converts the X-rays into digital signals. The unit can acquire still and moving images.

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Intended Use and Indications	The URS-50RF is indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures. It is also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. It is intended to replace fluoroscopic images obtained through image intensifier technology. Not intended for mammography applications.
Technological Characteristics and Substantial Equivalence	Comparison with the predicate shows the technological characteristics of the URS-50RF are equal to or better than the predicate device. The units are functionally identical.
Performance Testing/Data	Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device. Tests include: Performance testing and Software Validation. Electrical safety and Electromagnetic Compatibility testing has been performed. The unit complies with the US Performance Standard for radiographic equipment.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

JUL 30 2012

Re: K093688

Trade/Device Name: Canon Dynamic/Static DR Model URS-50RF

Fluoroscopic Digital X-Ray System

Regulation Number: 21 CFR 892.1650

Regulation Name: Image-intensified fluoroscopic x-ray system

Regulatory Class: II

Product Code: OWB, JAA and IZI

Dated: November 24, 2009

Received: December 2, 2009

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of February 4, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

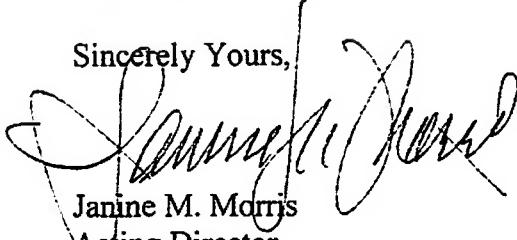
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris

Acting Director

Division of Radiological Devices  
Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

## INDICATIONS FOR USE

510(k) Number (if known): K093688

Device Name: Canon Dynamic/Static DR Model URS-50RF Fluoroscopic Digital X-Ray System

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Prescription Use  (Part 21 CFR 801 Subpart D)

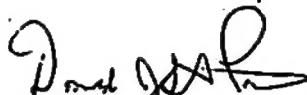
AND/OR

Over-The-Counter Use  (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of Radiological Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

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